OCT 24 2012 K120765

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Ortho-Clinical Diagnostics, Inc.
Address	100 Indigo Creek Drive Rochester, New York 14626
Phone number	(585) 453-3962
Fax number	(585) 453-3368
Establishment Registration Number	1319809
Name of contact person	Gaozhen Hang
Date prepared	March 12, 2012
Name of device	
Trade or proprietary name	VITROS Chemistry Products ECO_2 Slides
Common or usual name	Carbon Dioxide Test
Classification name	Bicarbonate/ carbon dioxide test system
Classification panel	Clinical Chemistry
Regulation	21 CFR 862.1160
Product Code(s)	KHS
Legally marketed device(s) to which equivalence is claimed	The VITROS Chemistry Products ECO_2 Slides (modified) are substantially equivalent to the VITROS Chemistry Products ECO_2 Slides (current). The FDA cleared the VITROS Chemistry Products ECO_2 Slides on April 24, 2000 (K001133).
Reason for 510(k) submission	A Special 510(k) for a modification to own device which does **not** include a change in intended use or fundamental technology. The biological source of Phosphoenolpyruvate carboxylase (PEPC), one of the reactive ingredients used in the VITROS Chemistry Products ECO_2 Slides is being changing from wheat germ to a microorganism. This change provides improved stability of enzyme solution while being used in the manufacture process.

Device description	The VITROS ECO_2 assay is performed using the VITROS Chemistry Products ECO_2 Slides and the VITROS Chemistry Products Calibrator Kit 2 on the VITROS Chemistry Systems. The VITROS ECO_2 Slide is a multi-layered, analytical element coated on a polyester support. The method is based on an enzymatic detection. All reactions necessary for a single quantitative measurement of CO_2 take place within the multi-layered analytical element of a VITROS Chemistry Products ECO_2 Slide. A drop of sample fluid is metered onto the slide and a reaction occurs which ultimately results in a reduction of NADH. The concentration of CO_2 in the sample is determined by measuring the absorbance of the unreacted NADH by reflectance spectrophotometry.
Intended use of the device	For *in vitro* diagnostic use only. VITROS Chemistry Products ECO_2 Slides quantitatively measure total carbon dioxide (CO_2) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.
Indications for use	For *in vitro* diagnostic use only. VITROS Chemistry Products ECO_2 Slides quantitatively measure total carbon dioxide (CO_2) concentration in serum and plasma using VITROS 250/350/950/5,1 FS, and 4600 Chemistry Systems and the VITROS 5600 Integrated System. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	New Device [VITROS ECO_2 Slide (Modified)]	Predicate [VITROS ECO_2 Slide (Current) [K001133]
Intended Use	No Change	For *in vitro* diagnostic use only. VITROS Chemistry Products ECO_2 Slides quantitatively measure total carbon dioxide (CO_2) concentration in serum and plasma using VITROS 250/350/950/5,1 FS, and 4600 Chemistry Systems and the VITROS 5600 Integrated System.
Basic Principle	No Change	Enzymatic Endpoint test type utilizing reflectance spectrophotometry

Concentrations of VITROS ECO_2 Slide Reactive Ingredients per cm-squared	Phosphoenolpyruvate carboxylase (microorganism E.C. 4.1.1.31) 0.20 U	Phosphoenolpyruvate carboxylase (**wheat germ** E.C. 4.1.1.31) 0.20 U
	No Change	Malate dehydrogennase (porcine heart E.C.1.1.1.37) 0.26 U; phosphoenolpyruvate 0.39 mg and nicotinamide adenine dinucleotide, reduced 0.44 mg
Sample volume	No Change	6 µL
Sample type	No Change	Serum, plasma
Assay Range Serum, Plasma	No Change	5.0-40.0 mmol/L
Incubation time and temperature	No Change	5 minutes at 37°C

Summary of design control activities conducted in relation to the device modification

The Ortho-Clinical Diagnostics, Inc. procedure for risk management is based on ISO 14971, Medical Devices – Application of Risk Management to Medical Devices and references CDRH Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management.
The risk analysis method used to assess the impact of the device modification was a Hazard Analysis. The following performance characteristics: accuracy, precision, linearity, potential interferents, long term and on-analyzer stability, limit of detection and specimen type were considered for potential hazards. Validation and verification testing were conducted and the modified device met the pre-determined acceptance criteria for all the performance testing.The modification does not negatively impact the performance of the device or the safety and effectiveness of the device.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The information presented in the premarket notification provides a reasonable assurance that the VITROS Chemistry Products ECO_2 Slides (modified) for use with human serum and plasma is substantially equivalent to the predicate (unmodified VITROS ECO_2 Slide) and is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Ortho-Clinical Diagnostics, Inc
c/o Gaozhen Hang
100 Indigo Creek Drive
Rochester, NY 14626-5101

OCT 24 2012

Re: k120765
Trade Name: VITROS® Chemistry Products ECO_2 Slides
Regulation Number: 21 CFR §862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Codes: KHS
Dated: September 27, 2012
Received: October 1, 2012

Dear Ms. Hang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH'S Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-576-. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800 638-2041 or (301) 796-5680 or at its Internet address http://www.fda/gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K120765

Device Name: VITROS® Chemistry Products ECO_2 Slides

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products ECO_2 Slides quantitatively measure total carbon dioxide (CO_2) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120765